510(k) Summary

Apex Knee™ Modular Tibia System

Submitter

OMNI life science, Inc.
50 O'Connel Way
E. Taunton, MA 02718

Contact

Brandon Molina
Regulatory Affairs
774.226.1815
508.822.6030 (fax)

OCT 0 8 2013

Preparation Date

5/14/2013

Device Name

Apex Knee™ Modular Tibia System

Common/Classification Name

Knee joint patellofemorotibial polymer/metal/ polymer semi-constrained cemented prosthesis

Regulatory Class

Class II per 21 CFR §888.3560, 888.3565

Product Code

JWH, MBH

Legally Marketed Predicate Device(s)

K101994 - Apex Knee Modular Tibia System cleared September 28, 2010

Device Description

The Apex Knee Modular Tibia System is composed of a tibial baseplate that mates with a cap, keel or a stem.

Additionally the baseplate may be used with tibial augments and pegs. The components are used together to form a prosthesis for implantation.

Indications For Use

The Apex Knee™ System is intended for use as a primary or revision total knee replacement. This prosthesis may be used for the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed;

The porous coated femoral component may be used cemented or uncemented (biological fixation). The porous coated tibial baseplate component may be used uncemented (biological fixation). All other femoral, tibial baseplate and patellar components are indicated for cemented use only.

The Apex Knee™ Modular Tibia System Tibial Augments are intended to be bolted to the Tibia Baseplate and cemented to the prepared tibia. The Apex Knee Revision Femur system augments are intended to be bolted to the femoral component and cemented to the prepared femur.

Predicate Devices Comparison

The subject device is substantially equivalent to its predicate based on comparison of design features, intended use, indications for use, materials, sterilization and shelflife. The safety and effectiveness of the Apex Knee System is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

Non-Clinical Test Summary

The following tests were conducted:

- Packaging Seal per ASTM F1929
- Tray Fatigue Strength Testing per ASTM F1800-07
- Tray-Augment Fret Testing per ASTM F1800-07
- Tray-Augment Attachment Strength testing per ASTM F1814-Shear
- Tray-Stem Attachment Testing per ASTM F1814: Axial, F1814: Torsion
- Stem and Augment Bolt retention testing
- Modular Stem Femur vs Tibia Loading Comparison per ASTM F1800-07

Clinical Test Summary

No clinical studies were performed.

Conclusions	The Apex Knee™ Modular Tibia System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 8, 2013

OMNI Life Science, Incorporated
Mr. Brandon Molina
Regulatory Affairs
50 O'Connel Way
East Taunton, Massachusetts 02718

Re: K131472
Trade/Device Name: Apex Knee™ Modular Tibia System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.
Regulatory Class: Class II
Product Code: JWH, MBH
Dated: August 7, 2013
Received: August 8, 2013

Dear Mr. Molina:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Not Known K131472

Device Name: Apex Knee™ Modular Tibia System

The Apex Knee™ System is intended for use as a primary or revision total knee replacement. This prosthesis may be used for the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed;

The porous coated femoral component may be used cemented or uncemented (biological fixation). The porous coated tibial baseplate component may be used uncemented (biological fixation). All other femoral, tibial baseplate and patellar components are indicated for cemented use only.

The Apex Knee™ Modular Tibia System Tibial Augments are intended to be bolted to the Tibia Baseplate and cemented to the prepared tibia. The Apex Knee Revision Femur system augments are intended to be bolted to the femoral component and cemented to the prepared femur.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices